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## Notice of Allowability

| Application No.           | Applicant(s)      |  |  |
|---------------------------|-------------------|--|--|
| 09/987,357                | CARMICHAEL ET AL. |  |  |
| Examiner                  | Art Unit          |  |  |
| Gerald G Leffers Jr., PhD | 1636              |  |  |

|   | Gerald G Leffers Jr., PhD   | 1636  |                           |
|---|---|---|---------------------------|
| The MAILING DATE of this communication appear All claims being allowable, PROSECUTION ON THE MERITS IS (herewith (or previously mailed), a Notice of Allowance (PTOL-85) NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGOR OF THE NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGOR OF THE NOTICE OF THE NO | OR REMAINS) CLOSED in this apport of the appropriate communication<br>GHTS. This application is subject to                                | olication. If not include will be mailed in due     | ed<br>course. <b>THIS</b> |
| 1.   This communication is responsive to a phone interview of 2   | <u>/11/2004</u> .   |   |                           |
| 2. ☑ The allowed claim(s) is/are <u>25</u> .  |   |   |                           |
| 3. The drawings filed on 14 November 2001 are accepted by t   | he Examiner.  |   |                           |
| <ol> <li>Acknowledgment is made of a claim for foreign priority under a)</li></ol>  | been received. been received in Application No uments have been received in this i  | national stage applica                              |                           |
| 5. A SUBSTITUTE OATH OR DECLARATION must be submit INFORMAL PATENT APPLICATION (PTO-152) which give:  |   |   | OTICE OF                  |
| <ul> <li>6. CORRECTED DRAWINGS (as "replacement sheets") must (a) including changes required by the Notice of Draftsperson 1) hereto or 2) to Paper No./Mail Date</li> <li>(b) including changes required by the attached Examiner's Paper No./Mail Date</li> <li>Identifying indicia such as the application number (see 37 CFR 1.6 each sheet. Replacement sheet(s) should be labeled as such in the paper No./Mail DFPOSIT OF and/or INFORMATION about the depose attached Examiner's comment regarding REQUIREMENT F</li> </ul>   | Amendment / Comment or in the O  34(c)) should be written on the drawir e header according to 37 CFR 1.121(c) it of BIOLOGICAL MATERIAL n | ffice action of<br>ags in the front (not the<br>d). | ·                         |
| Attachment(s)  1. Notice of References Cited (PTO-892)  2. Notice of Draftperson's Patent Drawing Review (PTO-948)  3. Information Disclosure Statements (PTO-1449 or PTO/SB/08 Paper No./Mail Date  4. Examiner's Comment Regarding Requirement for Deposit of Biological Material   | 5. Notice of Informal Page 1. Interview Summary Paper No./Mail Date 7. Examiner's Amendm 8. Examiner's Stateme 9. Other                   | (PTO-413),<br>e<br>nent/Comment                     |                           |
|   |   | Gerald G Leffers Jr.<br>Primary Examiner            | , PhD                     |

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## **EXAMINER'S AMENDMENT**

Receipt is acknowledged of an After-Final Amendment, filed 1/30/2004. A Notice of NonResponsive Amendment was inadvertently and improperly mailed on 2/3/2004. In a telephonic interview with Mr. William Straus on or about 2/11/2004, the examiner determined that the Notice was sent in error. This interview constitutes an acceptable response to the Notice of NonResponsive Amendment mailed 2/3/2004.

The reply filed 1/30/2004 has been has been considered and the amendment entered into the file. Following the response of 1/30/2004, only claim 25 remains pending and under consideration in the instant application. An examiner's amendment to claim 25 follows that puts the claim into condition for allowance.

An extension of time under 37 CFR 1.136(a) is required in order to make an examiner's amendment that places this application in condition for allowance. During a telephone conversation conducted on 2/25/2004, William Straus requested an extension of time for an additional 1 MONTH(S) and authorized the Director to charge Deposit Account No. 06-0916 the required fee of \$310 for this extension and authorized the following examiner's amendment. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

The application has been amended as follows:

In the claims:

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Claim 25. (currently amended) A purified collagenase inhibitor protein, said protein consisting essentially of an amino acid sequence selected from among the following:

- [(a) amino acid sequence SEQ ID NO: 2; or]
- [(b)] (a) the amino acid sequence of [a) or SEQ ID NO: 1 or of SEQ ID NO: 2, further having a Met at position -1; or
- [(c)] (b) the amino acid sequence of [a) or SEQ ID NO: 1 or of SEQ ID NO: 2, further having a leader sequence at the N-terminal, -1 position, wherein said leader sequence consists essentially of the following amino acid sequence from positions -38 to -1:

Gly His Arg Arg Arg Ser Ser Ala Gln Arg Asp Thr Arg Glu Pro Thr Met Ala Pro Phe Asp Pro Trp Leu Leu His Pro Val Val Ala Val Ala Asp Ser Pro Ser Arg Ala (SEQ ID NO: 3); or

[(d)] (c) the amino acid sequence of [a) or SEQ ID NO: 1 or of SEQ ID NO: 2, further having a leader sequence at the N-terminal, -1 position, wherein said leader sequence consists essentially of the following amino acid sequence from positions -22 to -1: Met Ala Pro Phe Asp Pro Trp Leu Leu His Pro Val Val Ala Val Ala Asp Ser Pro Ser Arg Ala (SEQ ID NO: 4).

## Reasons for Allowance

The following is an examiner's statement of reasons for allowance: the examiner's amendment obviates any potential rejection of claim 25 on the grounds that it is anticipated by the teachings of Stricklin et al (The Journal of Biological Chemistry, Vol. 258, No. 20, pages 12252-12258, 1983). Further, Stricklin et al do not make obvious the polypeptides encompassed Application/Control Number: 09/987,357

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by the allowed claim as it teaches only the first 20 or so amino acids of SEQ ID NO: 1 or SEQ ID NO: 2.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

## Conclusion

Claim 25 is allowed (now claim 1).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr., PhD whose telephone number is (571) 272-0772. The examiner can normally be reached on 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gerald G Leffers Jr., PhD

Primary Examiner Art Unit 1636

'GERRY LEFFERS'
PRIMARY EXAMINER